APR 4 - 2007

K 070108

510(K) Summary

Synvasive Technology, Inc.
4925 Robert J. Mathews Pkwy
El Dorado Hills, CA 95762
Phone: 916-939-3913
Contact: Michael G. Fisher
Date prepared: December 20, 2006

1. Trade Name: eLibra Dynamic Knee Balancer
Common Name: Orthopedic manual surgical instrument
Classification Name: Orthopedic manual surgical instrument, product code LXH,
Regulation: 888.4540 Class of device: Class I.

2. The legally marketed device to which we are claiming equivalence [807.92(a)(3)] : The Libra Dynamic Knee Balancer (510(k) exempt) manual orthopedic surgical instrument set.

3. Description of device: The device consists of two units, the force sensing unit and an electronic display. The eLIBRA™ Force Sensing Tibial Unit is a single use battery powered device designed to transmit an electronic signal to the eLIBRA™ Display Unit. The electronic signal represents the relative medial and lateral compartment forces generated from the soft tissue structures surrounding the knee joint during a total knee arthroplasty (TKA). The LIBRA Dynamic Knee Balancer eLIBRA™ Display Unit is a reusable battery powered device designed to receive an electronic signal from the eLIBRA™ Force Sensing Tibial Unit. The unit displays a number from 0-19 for both the medial and lateral compartments in the knee joint to aid the surgeon in balancing soft tissue structures during a total knee arthroplasty (TKA).

4. Intended use: For use as a tool for adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry. The force sensor is sterile, for single patient use.

5. Technological characteristics: The subject device differs from the predicate manual orthopedic device in that it employs a WIRELESS connection to the digital display unit.

6. Performance: Both bench and clinical tests were performed. Bench testing included mechanical testing, radio frequency, and sterility testing. including EO residues. Clinical testing was performed to determine adequacy of instructions for use, the range of patient population, performance characteristics, and reliability. The results were satisfactory and revealed no concerns over safety and effectiveness as compared to predicate devices. The tests demonstrated that the device is as safe, as effective, and performs in a substantially equivalent manner to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2009

Synvasive Technologies, Incorporated
% Michael G. Fisher
President and Chief Executive Officer
4925 Robert J. Mathews Pkwy.
El Dorado Hills, California 95762

Re: K070108
Trade/Device Name: eLibra Dynamic Knee Balancer
Regulation Number: 882.4560
Regulation Name: Sterotaxic instrument
Regulatory Class: II
Product Code: ONN
Dated (Date on orig SE ltr): April 4, 2007
Received (Date on orig SE ltr): April 4, 2007

Dear Mr. Fisher:

This letter corrects our substantially equivalent letter of April 4, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21

CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Division of Surgical, Orthopedic and
Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known):

Device Name: eLibra Dynamic Knee Balancer

Indications For Use:

For use as a tool for adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry. The force sensor is sterile, for single patient use.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucchi

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070108